

#96
Date
OFFICIAL

PTO/SB/21 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Applicati n Number	09/330,909	
	Filing Date	06/11/1999	
	First Named Inventor	Wolff	
	Group Art Unit	1632	
	Examiner Name	Joseph Voitach	
Total Number of Pages in This Submission	6	Attorney Docket Number	Mirus.011.01

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Declaration and notebook pages
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	Mark K. Johnson
Signature	/Mark K. Johnson/
Date	01/30/2003

CERTIFICATE OF MAILING			
I hereby certify that this correspondence is being sent by facsimile transmission to Joseph Voitach and addressed to: Commissioner for Patents, Washington, DC 20231 on this date:			
			01/30/2003
Typed or printed name	Mark K. Johnson		
Signature	/Mark K. Johnson/	Date	01/30/2003

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Hans Herweljer,
Jon A. Wolff, Larry F. Whitesell and
Matthew R. Wolff

Serial No.: 09/330,909

Filed: 6/11/99

Group Art Unit: 1632

Examiner: J. Weitach

For: A Process For Delivering Nucleic Acids To Cardiac Tissue

DECLARATION UNDER 37 C.F.R. §1.131

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

I, Jon A. Wolff, an inventor, hereby declare as follows:

1. I am an inventor of the captioned application and Director of a laboratory where intravascular delivery procedures have been performed under my direction.
2. I hereby submit laboratory notebook pages written by a scientist in my laboratory which describes our process of delivering nucleic acids prior to the filing date of the Mann et al. reference cited in the Office Action.
3. It is known to me and directed by me that the process performed in the notebook pages utilizes injecting a solution containing nucleic acids into a blood vessel lumen and increasing hydrostatic pressure in the lumen, and, delivering the nucleic acids to cells outside of the blood vessel via the increased pressure as described in the present specification.
4. It is known to me that the results shown in the notebook pages indicate expression in extravascular cells (cells outside the vessel).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Jon A. Wolff, M.D.

Date

1/30/03

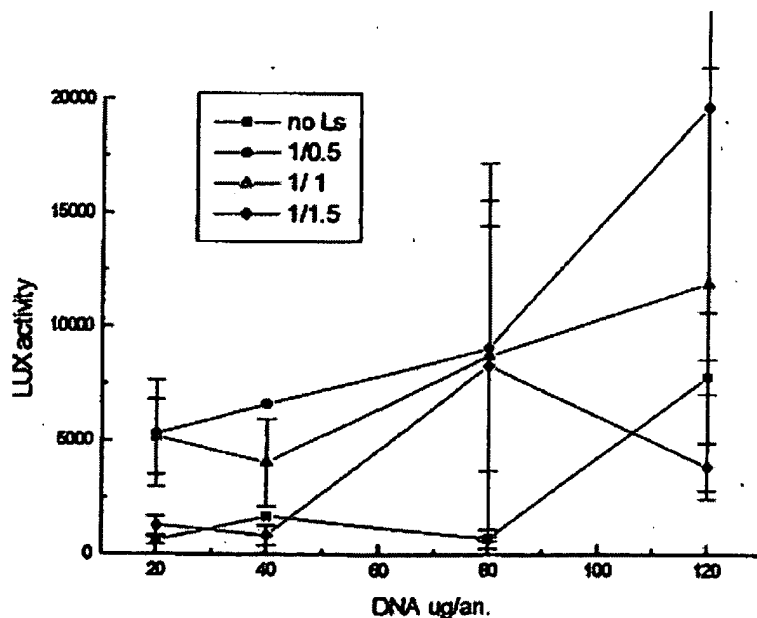
considered
7/27/03

2.3.95 February 3, 1995

Portal vein injection.

1 ml of SS with 20, 40, 80, 120 ug DNA and DOIm liposomes in molar ratio no, 1/0.5, 1/1 and 1/1.5 were injected into portal vein. After 2 days liver was divided at 4 fragments and assay was performed for every fragment as usually.

DN	no Ls	DNA/Ls 1/0.5	DNA/Ls 1/1	DNA/Ls 1/1.5
A				
20	645,645,880,598 768 607,571,558,710 446	1288,1873,1153,667 2982 6211,1673,938,835 7657	1083,3023,704,707 3517 4117,1399,1677,1649 6842	605,809,828,635 877 615,660,1701,715 1691
40	989,773,1198,716 1676	661,671,566,725 6623	1544,1437,3145,1829 5955 999,716,1653,773 2141	592,601,563,643 399 599,1351,701,638 1289
80	688,766,629,705 788 753,608,680,595 636	558,9904,4642,1346 14450 640,540,3591,934 3705	541,533,635,555 264 1896,15549,924,866 17235	617,735,665,1085 1103 10765,3060,1406,2360 15591
120	4318,1143,4016,1098 8575 786,6488,1063,735 7072	916,9281,1679,796 10672 1583,775,25483,2785 28626	888,1816,1012,724 2440 701,16534,4343,1835 21413	2324,1076,703,744 2847 2501,1552,1146,1699 4898



7/4/96 (120)

2.14.95

Intra Portal vein injection.

In all samples were DNA 120 ug, DOPE 120 ug. The temperature was 37.

Volume	- DOPE	+ DOPE
100 ul	615, 1275, 659, 3038 4087 1537, 798, 697, 683 2215	645, 1053, 683, 688 1569 786, 935, 1020, 928 2169
200 ul	604, 901, 951, 1100 2056	786, 771, 764, 888 1709 919, 527, 721, 1095 1762
400 ul	753, 683, 772, 999 1707 832, 668, 617, 746 1363	630, 1044, 768, 602 1544 1048, 718, 666, 573 1505
1000 ul	2802, 10195, 136502, 1198440 1346439 17339, 4258, 4566, 1476 26139	1676, 765, 599, 678 2218 1328, 8850, 1253, 985 10916

34/96 126

2.24.95

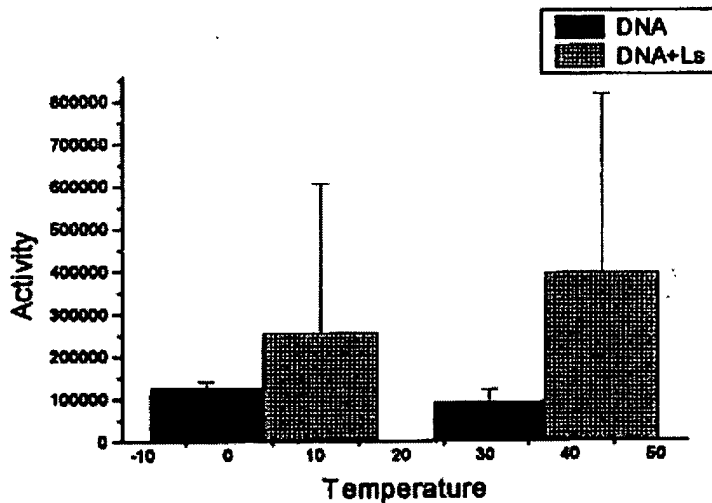
Liver injection (Liver vein clamp)

1 - 600 ug DNA in 150 ul + 5 ml NSS

2 - (600 ug DNA in 150 ul + 1 ml NSS) + (600 ug DOIm in 120 ul + 4 ml NSS).

100ul was injected in every animal.

Temper.	DNA	DNA + DOIm
4	1337,8688,88207,18461 115093	686,720,4223,3005 7034
	2888,1647,20986,112792 136713	116305,161599,74042,151765 502111
37	1776,95355,17053,4317 112564	19583,46174,20522,11267 95946
	2917,39136,24870,4096 69419	124518,198673,100938,267864 690393



3/4/96 (132)

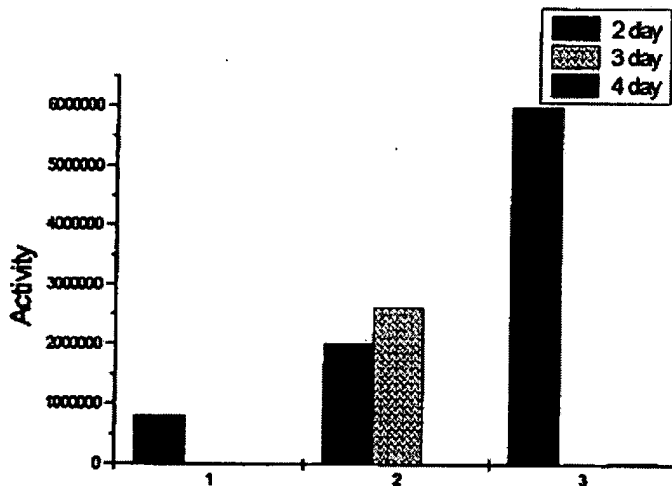
3.21.95

Intra liver Injection

- 1 - 120 ug DNA and 120 ug DOLm in 1 ml NSS
- 2 - 120 ug DNA and 120 ug DOLm in 1 ml Mannitol (20%)
- 3 - 120 ug DNA in 1 ml Man (20%)

The animals - C57

#	2 day	3 day	4 day
1	102572, 29674, 185567, 498422 815035		4784, 7352, 4717, 4556 20209 1210, 3651, 9097, 11477 24235
2	353919, 708213, 344504, 615769 2021205	206964, 228410, 1514843, 688541 2637558	1267, 1170, 1009, 964 3210
3	1410467, 3081579, 4514641, 2877893 11883380 58250, 33845, 31610, 31386 153891		8302, 63782, 16764, 4726 93374 2593, 5340, 6770, 2722 16225



3/4/96 JL (57)